IN THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

(Now known as Aventis (•)
	Plaintiff,)
	٧.	1:97CV1138
MONSANTO COMPANY, (Now known as Pharmacia Corp.),))
	and)
DEKALB GENETICS CORP.,)
	Defendants.	,) _)

MEMORANDUM OPINION

TILLEY, Chief Judge.

This Memorandum Opinion states the findings of fact and conclusions of law in connection with the trial held in this matter from August 22 to September 1, 2000. For the reasons outlined below, the Court finds that for patent 6,040,497 Rick DeRose, Georges Freyssinet, Michel Lebrun, Bernard Leroux, and Alain Sailland are entitled to be named as joint inventors; but for patent 5,554,798 it is determined that conception had occurred prior to any of the applicants making a significant inventive contribution and that their application should be denied. The Director of the Patent and Trademark Office will be directed to add those

individuals as joint inventors on the 497 patent.¹

I. PROCEDURAL HISTORY

Litigation between these parties has been extensive and complex. It has been ongoing for several years and prior proceedings include a lengthy trial on bifurcated issues. The Court's 136-page Memorandum Opinion, filed February 8, 2000 [Doc. #538], outlines the history of the case and the rulings made in connection with the previous trial.

As will be developed in this opinion, Rhône-Poulenc S.A. (now known as "Aventis CropScience S.A." but hereinafter referred to as "RPA") and DeKalb Genetics Corporation ("DeKalb") entered into a collaboration, informally in 1990 and formally in 1991, to develop glyphosate resistant corn. RPA's scientists were to find or develop genetic material which could add the trait of glyphosate resistance and DeKalb scientists were to use the material to "transform" corn by implanting it within cells which could be regenerated into fertile plants that would pass the trait to succeeding generations. During the collaboration, RPA's scientists constructed genetic material which was used by DeKalb in the transforming of corn and the regeneration and hybridizing of plants that were resistant to large, commercial applications of glyphosate.

¹ The title of the head of the Patent and Trademark Office changed from "Commissioner" to "Director" effective March 29, 2000. <u>See Fina Tech., Inc. v. Ewen</u>, 265 F.3d 1325, 1325 n.1 (Fed. Cir. 2001).

DeKalb contends that those glyphosate resistant plants, including that commercialized as "Roundup Ready®" Corn, are covered by the '497 and '798 patents.² The issue currently before the Court is whether one or more of the RPA scientists – Drs. Rick DeRose, Georges Freyssinet, Michel Lebrun, Bernard Leroux, and/or Alain Sailland – should be listed as co-inventors on either or both of those patents. Title 35 of the United States Code §256 authorizes a United States District Court to correct the inventors listed on U.S. patents.

The Court held a trial from August 22 to September 1, 2000 before an advisory jury.³ The jury found that for both of the patents at issue, RPA had proven the following by clear and convincing evidence: 1) that all five individuals contributed to the conception of the claims at issue⁴; 2) that the claims were the

² The two patents at issue are U.S. Patent 6,040,497 (known as the '497 patent) and U.S. Patent 5,554,798 (known as the '798 patent). Plaintiff initially contended that joint inventors should be listed on two additional patents, U.S. patents 6,025,545 and 5,990,390. However, the parties stipulated to the voluntary dismissal of those claims after the parties reached an agreement as to those matters [Docs. # 627 & 628].

The '497 patent claims four transformation events, including GA21 – the event upon which the glyphosate resistance of "Roundup Ready®" corn was based – which resulted from DeKalb's corn transformation process using RPA's DNA constructs. The '798 patent claims a fertile transgenic corn plant resistant to normally toxic levels of glyphosate.

³ RPA requested a jury trial. DeKalb claimed there was no right to a jury trial for an inventorship issue. The Court empaneled the advisory jury but stated that a final opinion would be issued by the Court. Neither party objected to the use of an advisory jury.

⁴ The claims at issue are claim 46 of the '497 patent and claim 1 of the '798 patent.

product of either a collaboration between RPA and DeKalb scientists or work under a common direction; 3) that the contributions of the five scientists were not insignificant in quality when measured against the dimension of the full inventions; 4) that the five individuals did more than contribute well known principles or explain concepts that are well known or the current state of the art [Doc. # 661]. More specifically, the jury found that the five individuals contributed to the '497 patent by providing DeKalb with significant DNA constructs that were successful at imparting glyphosate resistance in corn and which were included in the claimed transformation events GG25, GA21, GJ11, and FI117. In regard to the '798 patent, the jury found that the five individuals contributed to the conception of fertile transgenic corn containing DNA constructs encoding EPSP synthase that provide glyphosate resistance to corn.

The parties have submitted lengthy post-trial briefs suggesting findings of fact and conclusions of law. After reviewing the parties' filings and reviewing the evidence presented at trial, the Court now enters this Memorandum Opinion which will constitute its findings of fact, made by a clear and convincing standard, and its conclusions of law.

II. FINDINGS OF FACT

The findings relating to joint inventorship issues such as conception and inventive contributions are dependent upon an understanding of the scientific

problem or problems the parties were trying to resolve. Parts A and B of this section will address the object of the parties' undertaking and the pertinent science involved.

Α.

Glyphosate, manufactured and marketed by Monsanto Company⁵ as "Roundup®", is an effective and environmentally safe herbicide. Since its toxic action derives from the interruption of a plant's own food production occurring in the chloroplasts, it has no injurious effect on humans or other animals, and it biodegrades quickly in the soil. When applied in an appropriate amount, it is effective to kill all plants with green foliage. "Roundup Ready®" corn contains genetically engineered DNA making it resistant to glyphosate and enabling farmers to spray an entire field of corn, killing the weeds without adversely affecting the corn. Finding a way to impart glyphosate resistance to corn—the world's largest cash crop—was a long-term, worldwide effort of a number of researchers.

В.

Acting at the cellular level, the chemical structure of glyphosate allows it to bond in the chloroplast with EPSPS enzymes and, thereby, block the enzymes' necessary catalytic function in the plant's production of its own food.⁶ When a

⁵ Monsanto Company is now known as Pharmacia Corporation, but hereinafter referred to as "Monsanto."

⁶ "Glyphosate inhibits the shikimic acid pathway which provides a precursor for the synthesis of aromatic amino acids. Specifically, glyphosate curbs the

plant is subjected to glyphosate in amounts sufficient to prevent it from sustaining itself, it dies.

Specifically, the "string" of amino acids comprising a naturally occurring EPSPS enzyme (also referred to as an EPSPS "protein") forms a three dimensional, coil-like shape. Within the structure of the coil there is a "hole" or "cave" where, in the absence of glyphosate, a shikimate molecule and a PEP molecule fit and become bonded to form EPSP. When glyphosate is present, a molecule of glyphosate slips into the cave and bonds with the EPSPS enzyme in such a way as to block the PEP from entering. (DeRose, Trial Tr. vol. I, 113-16, 133.)

Once it was determined that glyphosate's toxicity related to bonding with EPSPS enzymes, the research objective was to find a shape for the enzyme that would allow PEP into the cave but block glyphosate. (Padgette, Trial Tr. vol IV, 579.) Modifications in the amino acid sequence of EPSPS enzymes in one type of plant would not necessarily be effective in others. (Padgette, Trial Tr. vol IV, 584.) For example, modifications which had imparted glyphosate resistance in soybeans or in tobacco had not successfully imparted it to corn, a monocot.

Modifications of an enzyme are not made at the enzyme level but to the gene which is ultimately responsible for the creation of the enzyme. (Freyssinet, Trial Tr. vol. IV, 626-27, 687.) Genes are DNA, located within the chromosomes

conversion of phosphoenolpyruvate ("PEP") and 3-phosphoshikimic acid ("shikimate") to 5-enolpyruvyl-3-phosphoshikimic acid ("EPSP") by inhibiting the enzyme 5-enolpyruvyl-3-phosphoshikimate synthase ("EPSPS")." (DTX1940 at 2.)

in the nucleus of a cell. Each functioning gene controls a specific process going on somewhere within the cell. An excellent description of the fundamental biochemistry involved in this process – also supported by the testimony in this case – is found in Mycogen Plant Science, Inc. v. Monsanto Co., 61 F. Supp. 2d 199 (D. Del. 1999), adopted by, Mycogen Plant Science, Inc. v. Monsanto Co., 243 F.3d 1316, 1323-24 (Fed. Cir. 2001):

Organisms, like plants and animals, are made up of cells. Genes are comprised of DNA (deoxyribonucleic acid), which encodes the necessary information for cells to reproduce and to produce specific proteins.

DNA consists of two long chains or strands that wrap around each other in a shape known as a double-stranded spiral helix. Visually, a molecule of DNA resembles a twisted ladder. The sides of the ladder are connected by rungs made up of pairs of molecules called nucleotides. Four different nucleotides, each containing one of the bases adenine ("A"), guanine ("G"), cytosine ("C") and thymine ("T"), form the particular DNA make-up of genes. A particular DNA molecule can be graphically represented by listing the nucleotide sequences making up that DNA molecule.

Because of the nucleotides' chemical make-up, A will only pair with T, and C will only pair with G. This strict complementary pairing means that the order of the nucleotides on one side of a DNA rung determines the order on the other side of the rung. Therefore, each rung of the ladder is composed of one pair consisting of A and T, or C and G. Each rung is called a nucleotide pair, and the order in which these nucleotide pairs appear on the DNA ladder constitutes the genetic code for the cell.

DNA directs cells to make proteins through a two-step process of transcription and translation. In the first step, transcription, information is transferred from DNA to an RNA, or ribonucleic acid, molecule. RNA that codes for a protein is called messenger RNA ("mRNA").

RNA is a long single strand of linked nucleotides similar to DNA. However, one of the differences between DNA and RNA is that RNA contains the base uracil ("U") in place of thymine. In transcription, specific nucleotide sequences on the DNA determine where the RNA copy begins and ends.

In the second step, translation, the nucleotide sequence of the mRNA is translated into the amino acid sequence of the corresponding protein. For this translation work, a complex structure known as a ribosome reads the mRNA nucleotide sequence and generates amino acids. These amino acids are then assembled into proteins. In this way, ribosomes carry out protein synthesis.

Ribosomes read a nucleotide sequence in sets of three nucleotides, known as codons. Each codon directs the ribosome to select a certain amino acid. For example, GCT is a codon directing the ribosome to select the amino acid alanine. Just as nucleotides are the basic units of DNA, amino acids are the basic units of proteins. Thus, a given series of codons specifies a sequence of amino acids comprising a particular protein. A protein can contain few or many amino acids. For example, some Bt pesticidal proteins contain more than 600 amino acids.

While there are 61 possible codons, there are only 20 amino acids. [FN1] Some amino acids can be specified by more than one codon. In other words, one codon can be substituted for another in the gene without changing the amino acid and resulting protein. For instance, the amino acid alanine is specified by four different codons: GCT, GCG, GCC and GCA. Two very different series of codons could produce the exact same series of amino acids. In fact, most amino acids are specified or coded by more than one codon. [FN2]

FN1. There are 61 codons because a codon is a sequence of three nucleotides. For mRNA, there are four nucleotide possibilities, A, G, C and U. Thus, three nucleotides, each consisting of four possibilities, A, G, C or U, are represented mathematically as 43 (4 x 4 x 4), which equals 64 possible codons. Of the 64 possible codons, however, three codons, UAA, UAG and UGA, do not correspond to amino acids. Thus, there are 61 codons. See, e.g., McGraw-Hill Encyclopedia of Science & Technology, "Gene" at Vol. 7, page 740 (1997). For general information on genetics, see In re O'Farrell, 853 F.2d 894, 895-99, 7 USPQ2d 1673, 1674-77 (Fed. Cir.1988).

FN2. Scientists variously refer to this as "redundancy" or "degeneracy" in the genetic code. The term "unique" refers to an amino acid coded by only a single codon. See, e.g., Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1207-08 n. 4, 18 USPQ2d 1016, 1022 n.4 (Fed. Cir. 1991).

Mycogen Plant Science, 61 F. Supp. at 207-08.

A gene "encoding an EPSPS enzyme" is a gene whose nucleotide sequence, following transcription⁷ in the nucleus and translation⁸ in the cytoplasm, results in the specific amino acid sequence of a protein or enzyme known, immediately after translation, as an "EPSPS precursor enzyme." As the ribosome is reading the codons and adding the amino acids specified, the precursor enzyme is folding, assuming the three dimensional, coil-like shape characteristic of that species' EPSPS enzyme.

A gene coding for an EPSPS protein in a plant (as opposed to a bacterium) also codes for an amino acid sequence known as a transit peptide. The transit peptide is attached to the amino acids of the EPSPS and has the function of targeting the protein to a chloroplast and accomplishing passage through the chloroplast wall. Upon entry into the chloroplast, the transit peptide portion is cleaved, leaving the "mature" EPSPS protein. (DeRose, Trial Tr. vol I, 123-31.)

One of the important regions of a gene's nucleotide sequence is the

⁷ In general terms, transcription is copying, by the structure known as RNA polymerase, from DNA chemistry into RNA chemistry.

⁸ In general terms, translation is copying, by the ribosome, from RNA chemistry into the amino acid sequence specified by the codons of nucleotides.

promoter. The promoter is the first part of a gene and acts as the "off/on switch," attracting the RNA polymerase structure in the nucleus to approach and begin the transcription phase, copying from the DNA into mRNA. The frequency with which the promoter attracts the RNA polymerase affects the number of proteins ultimately being translated. It also determines in what plant part the production of that protein will be more active. For example, in humans, promoters "tell[] the genes which make the hair and the fingernails to only make hair and fingernails where fingernails and hair are supposed to be made." (DeRose, Trial Tr. vol I, 122-24.)

These processes within a plant cell are central to the research and development of glyphosate resistance in corn.

C.

RPA is a worldwide manufacturer and vendor of diversified agricultural products, and is engaged in chemical and biotechnological research and development with particular interests in the area of weed control and crops.

Monsanto manufactures and sells a diversified line of agricultural products as well, including herbicides, and is engaged in biotechnological research and development.

DeKalb, which became a fully-owned subsidiary of Monsanto in December 1998, is involved in agricultural genetics and biotechnology for corn seed, and is one of the largest corn seed suppliers in the United States.

From the mid-1980s, researchers, including those from RPA, DeKalb,

Calgene⁹, and Monsanto had worked to identify a means to impart glyphosate resistance to commercial crops so that farmers could spray an entire field with glyphosate, kill unwanted vegetation, and leave their crop unaffected. In that time frame, both RPA and DeKalb were collaborating with Calgene. Calgene's role was significant at the time because Dr. Luca Comai, a Calgene scientist, had identified CT7 (also referred to as the "aroA"), a mutagenized EPSPS gene in the bacteria Salmonella typhymurium which showed some resistance to glyphosate. Dr. Comai had published his work with CT7 in 1985 and hope existed that his success in finding the gene would lead to further success in imparting glyphosate resistance to crops. (DeRose, Trial Tr. vol. II, 308-10.)¹⁰

⁹ Non-party Calgene, Inc. ("Calgene") was primarily a biogenetic research company.

¹⁰ One of DeKalb's arguments at trial was that Dr. Comai, not the RPA scientists, should receive sole inventive credit for certain of the contributions to the inventions claimed in the patents at issue here. RPA contends that DeKalb is collaterally estopped from making this claim based on a binding arbitration that took place between Calgene and RPA. The Arbitration Award in that case, Calgene LLC v. Rhone-Poulenc Agro S.A., AAA Case No. 50T1530019099 (the "Arbitration), stated in part that neither Dr. Comai nor anyone else at Calgene contributed to the OTP, the DMMG, or RD-125. However, one of the elements of collateral estoppel is that the "determination of the issue must have been a critical and necessary part of the decision in the prior proceeding." Sedlack v. Braswell Servs. Group, Inc., 134 F.3d 219, 224 (4th Cir. 1998). Courts applying this element of collateral estoppel have found that when cases are dismissed on alternative grounds, one procedural and one substantive, the substantive ground is dicta and therefore not collaterally estopped in future litigation. See Pizlo v. Bethlehem Steel Corp., 884 F.2d 116, 119 (4th Cir. 1989) ("When a dismissal is based on two determinations, one of which would not render the judgment a bar to another action on the same claim, the dismissal should not operate as a bar.") (citing Restatement (Second) of Judgments § 20); Tuttle v. Arlington County Sch.

Dr. Comai had isolated CT7 by treating the bacteria with ethyl methane sulfonate (EMS), a compound capable of causing random changes in the DNA of the bacteria. (Freyssinet, Trial Tr. vol. IV, 594.) He identified CT7 as a gene with a mutation in which the amino acid Serine had been substituted for the amino acid Proline at the "101" position (noted as "Pro + Ser, 101"). (DeRose, Trial Tr. vol. II, 327 & vol. I, 138-39; Lebrun, Trial Tr. vol. III, 542; Freyssinet, Trial Tr. vol. IV, 666-68; Comai, Trial Tr. vol. V, 854-57.)

In the collaboration between RPA and Calgene, Calgene provided the CT7 and did most of the research to find new, more resistant genes. RPA did much of the research to develop more effective transit peptides and promoters that would enhance the resistance of the genes. In addition, RPA provided most of the funding. A Scientific Committee comprised of two members each from Calgene and RPA oversaw the scientific work of the collaboration.

When experiments with CT7 were proving unsuccessful, the Scientific Committee directed further experiments that led to the development of B808, another randomly mutagenized aroA bacterial gene. B808 encoded an EPSPS enzyme with three mutations, one of which was a Threonine to Isoleucine mutation

<u>Bd.</u>, 195 F.3d 698, 704 (4th Cir. 1999). In this case, the Arbitration Award relied upon by RPA cited several different grounds – including Calgene's lack of standing to bring its claims and the expiration of the applicable New York statutes of limitations – as reasons for the denial of Calgene's claim. Because the Arbitration's discussion of Dr. Comai's contributions were alternative grounds to its denial of Calgene's claims on procedural grounds, it will not be afforded preclusive effect in this case. <u>See id.</u>

at the "97" position (Threo + Iso, 97). (Freyssinet, Trial Tr. vol. IV, 596, 597-98, 609; Comai, Trial Tr. vol. V, 859.) The B808 gene was more successful in vitro than CT7 at imparting glyphosate resistance. More experimentation began in 1989 at both Calgene and RPA to learn whether the Threo + Iso, 97, was the substitution conferring resistance.

The use of plant EPSPS genes – in addition to bacterial EPSPS genes – for mutagenesis had been discussed from time to time both within Calgene and within RPA. (Lebrun, Trial Tr. vol. III, 521-24.) Additionally, the idea had been debated during meetings between RPA and Calgene, but Dr. Comai had never made a concrete proposal to pursue the idea. (Comai, Trial Tr. vol. V, 876-77, 886). Instead, he had elected to continue research with the Salmonella gene. (Comai, Trial Tr. vol. V, 877, 879-81, 888-89.)

At a committee meeting between Calgene and RPA, Dr. Comai suggested site mutagenesis of a wild type bacterial EPSPS gene by combining the Pro Ser, 101 mutation from the CT7 AroA gene with the Threo Iso, 97 mutation from the B808 randomly mutated bacterial gene. (Comai, Trial Tr. vol. V, 863-67; DTX 1477 at RPA 031676 & 031685.) At the meeting, Dr. Freyssinet proposed that RPA would mutate a maize gene. (Comai, Trial Tr. vol. V, 893; DTX 1477 at RPA 031676.)

¹¹ In vitro testing involved isolating the enzyme from the bacteria and observing reactions in a test tube.

As Calgene was beginning the process of combining the "97" and "101" mutations, it was discovered that B808 was toxic to the E. coli bacteria in which it was being cloned. (Freyssinet, Trial Tr. vol. IV, 616-17.) The minutes of the October 1989 RPA-Calgene Scientific Committee stated that B808 was "clearly the worst" in terms of toxicity and that "Toxicity to E. Coli is triggered by 97 thr isoleu mutation." (PTX 1431 at CAL 004229.) By the end of 1989, Calgene and RPA had determined that no progress had been made with the bacterial aroA genes. (PTX 1431 at CAL 004229.) Dr. Comai left Calgene, and technical collaboration between RPA and Calgene on glyphosate resistance ended in 1989.

DeKalb also had an ongoing collaboration agreement with Calgene around the same time. In 1990, RPA and DeKalb began an informal collaboration with the ultimate goal of genetically altering corn to make it commercially resistant to glyphosate. In 1991, RPA, DeKalb, and Calgene entered into an "Assignment and Assumption Agreement" (the "1991 Agreement"), in which RPA assumed Calgene's rights and obligations under DeKalb's 1985 Agreement with Calgene. RPA performed the molecular biology research work by creating various genetic constructs, initially with the CT7. Then, DeKalb "transformed" corn cells by using the microprojectile bombardment method. This called for coating microprojectiles

¹² This method was originally described by Ronald C. Lundquist and David A. Walters, who worked for the research company Biotechnica, in a January 1990 patent application 467,983. However, through a serious of asset transfers, the application became the property of DeKalb and ultimately gave rise to the '798 patent.

such as gold particles with the new DNA, firing the particles with a "gene gun" into a callus of embryonic maize cells on a petri dish, selecting and growing cells which had actually integrated the new DNA, testing in vitro, regenerating transformed cells into plants which, if fertile, would be crossed to create a second generation (the R-1 generation) and testing R-1 plants within the greenhouse and, then, in the field. At each stage, DeKalb tested the transformed cells and plants for glyphosate resistance. Neither party had the capability to perform the other party's role in this collaboration, and both roles were necessary in order to produce glyphosate resistant corn.

Under this collaboration, genetic material other than the CT-7 gene was transferred from one company to the other. On June 17, 1991, at the first joint meeting of RPA and DeKalb after the 1991 Agreement was signed, the companies agreed that any material transferred between the companies would be subject to a Confidentiality Agreement originally entered into by Calgene and DeKalb in 1984.

Experiments with CT7, however, continued to show that the CT7 gene did not impart sufficient glyphosate resistance in corn to be useful either as a selectable marker¹³ in vitro, or to impart sufficient glyphosate resistance to a

¹³ A selectable marker is identifiable genetic material which may be included with other DNA in a transformation process to show which cells may have incorporated the new DNA; however, post transformation presence of a selectable marker would not necessarily indicate that the trait associated with the new DNA had been imparted to any particular level. "Useful selectable markers are well known in the art and include, for example, antibiotic and herbicide resistance genes Other selectable markers include . . . those genes which code for resistance

transformed corn plant that it could withstand an application of glyphosate more than one-fourth that recommended as sufficient to kill easy to control weeds¹⁴ without being killed or stunted. (PTX 240 at DKB 040279-040281; PTX166 at DKB 056725.)

In 1988, Monsanto's European patent application, PTX 1940, disclosed, among other things, that modifying maize EPSPS DNA to encode a protein with a mutation from Glycine to Alanine at position 101 would provide some glyphosate resistance in corn. (DeRose, Trial Tr. vol. I, 168-70 & vol. II, 312-17; Quatrano, Trial Tr. vol. VI, 1006-07; DTX 1940.)

The formal collaboration between DeKalb and RPA lasted from June of 1991 to November of 1992 and included organized meetings of a Scientific Committee comprised of members from DeKalb and RPA. Throughout the collaboration, proposals were made by the Committee to determine what experiments should be done.

Consistent with Dr. Freyssinet's statement at one of the final RPA/Calgene Committee meetings, RPA scientists Lebrun, Sailland and Freyssinet had the idea of using the mutation from the CT7 bacterial aroA gene (Proline + Serine at the 101 position) and one of the three mutations from the B808 bacterial aroA gene

or tolerance to glyphosate." (U.S. Patent No. 5,554,798, col.9, II.11-22.)

¹⁴ The recommended amount is 16 ounces per acre. (PTX 240 at DKB 040279.)

(Threonine ÷ Isoleucine at the 97 position) in the amino acid sequence of a maize EPSPS gene from the cell line developed by Dr. Freyssinet. (Lebrun, Trial Tr. vol. III, 525-28, 54, 548-49 & vol. IV, 572-73.) The idea was that, perhaps, the mutations would be more successful at imparting glyphosate resistance in RPA's maize gene and, perhaps, the mutation from B808 would not be toxic to the maize gene. The gene was known as the "double mutant maize gene" ("DMMG") because of the two mutations – Threonine ÷ Isoleucine at the 102 position and Proline ÷ Serine at the 106 position.

Throughout the RPA/DeKalb collaboration (June 1991 to November 1992), approximately four Scientific Committee meetings took place in which information on projects was shared between the companies. In November 1992, Dr. Freyssinet attended the last of these four meetings. (Freyssinet, Trial Tr. vol. V, 733.) At that meeting, Dr. Freyssinet indicated that RPA would not put any further effort into molecular biology research for glyphosate resistance but agreed to provide to

¹⁵ RPA was involved in a project around 1986, independent of its collaboration with Calgene, which sought to create a glyphosate resistant corn line that could potentially be regenerated into glyphosate tolerant corn. This special corn line was not capable of producing glyphosate resistant corn, but had an increased concentration of EPSPS genes, which allowed RPA to isolate a maize EPSPS gene from the culture. (Freyssinet, Trial Tr. vol. IV, 613-14; see also DeRose, Trial Tr. vol. II, 209.) Drs. Lebrun, Sailland and Freyssinet had conceived of the idea to try the two specific mutations in a maize EPSPS gene of that line instead of the Salmonella gene. Another mutation used in these experiments was Monsanto's patented Gly ♣ Ala mutation at the 101 position. (Lebrun, Trial Tr. vol. III, 525-28, 548-49 & vol. IV, 572-73.) Dr. Freyssinet contributed to the isolation of the maize gene used for the DMMG. (DeRose, Trial Tr. vol. I, 156-59.)

DeKalb the new genetic material containing mutated EPSPS maize genes. 16 (Freyssinet, Trial Tr. vol. V, 748.)

When Dr. Freyssinet returned from the meeting, he requested that Dr. Rick DeRose, an RPA scientist, prepare various constructs using the single and double mutated maize genes to send to DeKalb. Dr. DeRose prepared and sent five different constructs to DeKalb in February 1993. Three included the new double mutant maize gene, DMMG (Threo÷lso at 102 and Pro÷Ser at 106). Two included the single mutant (SMMG) (Gly ÷ Ala at 101) referred to earlier as the Monsanto mutation. (PTX 142 at DKB 040519; DeRose, Trial Tr. vol. I, 165-68, vol. II, 218-21 & vol. III, 419-20; Spencer, Trial Tr. vol VII, 1137-40.) The DNA constructs comprised either the DMMG or the SMMG along with other components variously included to target and enter the chloroplast and cut the portions - the "met"- once in the chloroplast. Some included promoters. One of the constructs, RD-125, contained the DMMG, a transit peptide developed by RPA known as the "Optimized Transit Peptide" ("OTP")¹⁷, a methionine ("met") added at the cleavage

¹⁶ At the time of the November 1992 meeting, RPA had discovered from field trials in the summer of 1992 that the maize gene was giving better results in tobacco than the bacterial one. At that time (summer 1992), RPA had only tested the Monsanto Gly ♣ Ala single mutant. In the fall of 1992, RPA knew that the maize gene was giving better results than the bacterial one. (Freyssinet, Trial Tr. vol. V, 735-36.)

¹⁷ RPA had developed the Optimized Transit Peptide ("OTP") to enhance glyphosate resistance by better targeting the chloroplast and accomplishing a more effective cleavage site from the enzyme. Drs. Lebrun, Leroux and Sailland created the OTP and are the named inventors on the patent. (Lebrun, Trial Tr. vol. IV,

site to promote stability, and a "stop" known in the art as NOS. Dr. Freyssinet and Dr. DeRose suggested that DeKalb also use a Rice Actin Promoter¹⁸ in connection with some of the constructs RPA provided. (Freyssinet, Trial Tr. vol. IV, 660-63.) All of the constructs¹⁹ were sent to DeKalb for the purpose of transforming corn cells and with the goal of creating glyphosate resistant corn.

DeKalb used the gene gun transformation process to insert the various constructs into the corn calli. The precise points at which the constructs integrate, if at all, into the corn genome are random and cannot be controlled. After the constructs have been introduced with the gene gun, the random but fixed integration of the DNA into the chromosome is the transformation event and each event is labeled individually for identification.²⁰ The four "key" transformation events that resulted from insertion of RD-125 are labeled as: GA21, FI117, GJ11,

515-17; DTX 1257.)

¹⁸ The Rice Actin Promoter invented and patented by Ray Wu of Cornell University was acquired by DeKalb and used with RD-125 (OTP, Met, DMMG and NOS) in the constructs that became transformation events GA21 and FI117. Other promoters - a "maize histone promoter" and a "hybrid 35S/Arabidopsis histone promoter" were also used in constructs with RD-125. Transformation event GG25, discussed <u>supra</u>, used a maize histone promoter and GJ11, discussed <u>supra</u>, used the hybrid 35S/Arabidopsis histone promoter.

 $^{^{19}}$ The other constructs – RD-123, RD-129, RD-130 and RD-131 – were sent to DeKalb in addition to RD-125. RD-125 and RD-130 created key transformation events, but RD-125 was ultimately the construct used for "Roundup Ready®" corn.

²⁰ The parties stipulated to the legal construction of the term "transformation event" as "a plant or seed which has a specific DNA cassette in a specific location somewhere within the chromosome of the corn cell."

and GG25.²¹

The transformation events DeKalb created using RPA's constructs were crossed with another corn line, creating a hybrid plant. (DeRose, Trial Tr. vol. II, 242.) In late 1993 and early 1994, in a greenhouse, DeKalb succeeded in growing transformed corn plants that contained RPA's RD-125 construct and were resistant to Roundup® herbicide at potentially commercial levels. Those hybrid plants were then tested in the field in Hawaii in September 1994. The field tests showed that the corn plants resulting from the four transformation events (FI117, GA21, GG25, and GJ11) were resistant to glyphosate when four times the normal commercial application rate was applied.²² GA21 was the event of choice after extensive testing with regenerates from these four transformation events. (Armstrong, Trial Tr. vol. III, 483-84; Quatrano, Trial Tr. vol. VI, 999 ("I think in almost all cases we end up putting a particular construct in to look at its expression, whether it is GA21 or FI117 or any other construct, that one has to look at a fairly large number of regenerates to actually see or to select out those that have a fairly high expression level, due primarily, we believe, to the position in which the DNA is inserted.").)

The relevant facts concerning the patents that arose from these activities are discussed below.

²¹ These events are claimed in the '497 patent.

²² The normal application rate was 16 ounces per acre. Other plants in the trials were completely killed at the application rate of 16 ounces per acre.

III. INVENTORS

Patents are presumed to be valid and name the correct inventors. <u>Canon</u>

<u>Computer Sys., Inc. v. Nu-Kote Int'l Inc.</u>, 134 F.3d 1085, 1088-89 (Fed. Cir.

1998). This presumption can only be overcome by clear and convincing evidence.

<u>See Applied Med. Res. Corp. v. U.S. Surgical Corp.</u>, 967 F. Supp. 867, 871 (E.D. Va. 1997); <u>Burroughs Wellcome Co. v. Barr Labs. Inc.</u>, 828 F. Supp. 1200, 1204 (E.D.N.C. 1993) (citing <u>Amax Fly Ash Corp. v. United States</u>, 514 F.2d 1041, 1047 (Cl. Ct. 1975)). However, a party may allege, as Plaintiff has here, that it was omitted from the named inventors under 35 U.S.C. §256²³:

Whenever...through error an inventor is not named in an issued patent and such error arose without any deceptive intention on his part, the Director may, on application of all the parties and assignees, with proof of the facts and such other requirements as may be imposed, issue a certificate correcting such error.

. . . The court before which such matter is called in question may order correction of the patent on notice and hearing of all parties concerned and the Director shall issue a certificate accordingly.

Currently, the law is that a finding that inventors have been omitted from those listed on the patent does not necessarily invalidate the patent. See 35 U.S.C. § 256 ("The error of omitting inventors or naming persons who are not inventors shall not invalidate the patent in which such error occurred if it can be corrected as provided in this section."); see also Pannu v. lolab Corp., 155 F.3d 1344, 1350 (Fed. Cir. 1998); Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1461 (Fed. Cir. 1998) ("35 U.S.C. § 256 provides that a co-inventor omitted from an issued patent may be added to the patent by a court before which such matter is called in question.") (internal citations omitted). Additionally, in Pannu v. lolab, the Federal Circuit found that a party subject to a claim of invalidity could invoke § 256 to "save" the patent. 155 F.3d at 1350. In this case, however, invalidity is not asserted.

Id. Here, Plaintiff has called into question the omission of scientists it alleges are joint inventors on both the '497 and the '798 patents. The only procedural requirements for a correction of inventorship action in district court are notice and an opportunity to be heard. Id.; see also Stark v. Advanced Magnetics, Inc., 119 F.3d 1551, 1553 (Fed. Cir. 1997). Both have been provided in this case.

Therefore, the Court, if it is appropriate under the facts, may order correction of the patent. MCV, Inc. v. King-Seely Thermos Co., 870 F.2d 1568, 1570 (Fed. Cir. 1989) ("Section 256 . . . explicitly authorizes judicial resolution of co-inventorship contests over issued patents. . .").

With respect to joint inventorship, the Federal Circuit has said:

All that is required of a joint inventor is that he or she (1) contribute in some significant manner to the conception or reduction to practice of the invention; (2) make a contribution to the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention; and (3) do more than merely explain to the real inventors well-known concepts and/or the current state of the art.

²⁴ A correction of inventorship action involves questions of law and therefore does not require a jury trial. <u>See Ultra-Precision Mfg., Ltd. v. Ford Motor Co.</u>, 411 F.3d 1369, 1376 (Fed. Cir. 2005). In this case, an advisory jury was empaneled and the parties were advised that the final opinion would be issued by the Court. <u>See Tamko Roofing Prod., Inc. v. Smith Eng'g Co.</u>, 450 F.3d 822, 828 (8th Cir. 2006) (explaining when a jury sits in a solely advisory capacity the court is free to accept or reject its findings); <u>Cox v. Babcock & Wilcox Co.</u>, 471 F.2d 13, 14 (4th Cir. 1972) (noting findings of advisory jury are merely advisory and the court must make its own findings); <u>Sheila's Shine Prod., Inc. v. Sheila Shine, Inc.</u>, 486 F.2d 114, 122 (5th Cir. 1973) ("[The trial court] is not bound by the findings of the advisory jury, which it is free to adopt in whole or in part or to totally disregard."). Neither party in this case objected to the use of an advisory jury.

Pannu v. lolab Corp., 155 F.3d 1344, 1351 (Fed. Cir. 1998). Joint inventors must also be working in collaboration. See Kimberly-Clark Corp. v. Proctor & Gamble Distrib. Co., 973 F.2d 911, 917 (Fed. Cir. 1992) (holding that joint inventorship requires some level of collaboration). However, "[t]he question of whether a person is a joint inventor is fact specific, and no bright-line standard will suffice in every case." Fina Oil & Chem. Co. v. Ewen, 123 F.3d 1466, 1473 (Fed. Cir. 1997). Therefore, the facts of this case will be reviewed with respect to each patent to determine whether there is clear and convincing evidence that RPA's five scientists meet the standard for joint inventorship.

An inventorship analysis, like an infringement analysis, begins with a construction of each asserted claim. See Markman v. Westview Instruments, Inc., 52 F.3d 967, 996 n.7 (Fed. Cir. 1995) (Mayer, J., concurring), aff'd, 517 U.S. 370 (1996). After each asserted claim is construed, the second step is then to compare the alleged contributions of each asserted co-inventor with the subject matter of the properly construed claim to determine whether the correct inventors were named. Ethicon, Inc. v. U.S. Surgical Corp., 135 F.3d 1456, 1460 (Fed. Cir. 1998). Thus, the construction of each of the patents will first be discussed, followed by a determination of whether joint inventorship is appropriate under the standard set forth above.

A. The '497 Patent

1. Claim Construction

The first patent for which RPA seeks to have its five scientists declared joint inventors is the '497 patent or "Spencer patent". For present purposes, the crucial claim in the '497 patent is claim 46, which reads as follows:

A glyphosate resistant, hybrid maize plant comprising a chromosomally integrated expression cassette comprising (a) a modified maize EPSPS gene encoding an EPSPS protein having isoleucine at position 102 and serine at position 106 and (b) a promoter active in maize operably linked to said EPSPS gene, wherein said hybrid maize plant comprises a transformation event selected from the group consisting of GA21, seed comprising said GA21 transformation event having been deposited as ATCC Accession Number 209033, FI117, seed comprising said FI117 transformation event having been deposited as ATCC Accession Number 209031,GG25, seed comprising said GG25 transformation event having been deposited as ATCC Accession Number 209032, and GJ11, seed comprising said GJ11 transformation event having been deposited as ATCC Accession Number 209030.

('497 Patent, col.64, II.58 - col.65, II.4.)

The parties have agreed on the proper construction of this claim.

Specifically, they have agreed to the following construction:

The phrase "[a] glyphosate resistant, hybrid maize plant" means a hybrid corn plant that provides the level of glyphosate resistance provided by one of the four specifically identified transformation events. A hybrid corn plant is a cross of two different genotypes of corn, which are sometimes called the "parents" of the hybrid corn plant.

Because the four specifically identified transformation events already include (a) a modified maize EPSPS gene encoding an EPSPS protein having isoleucine at position 102 and serine at position 106 and (b) a promoter active in maize operably linked to said EPSPS gene, the claimed hybrid corn plant must have as one of its parents one of

the four transformation events discussed below. A transformation event is a plant or seed which has a specific DNA cassette in a specific location somewhere within the chromosome of the corn cells.

The specific transformation events are identified by the phrase "GA21, seed comprising said GA21 transformation event having been deposited as ATCC Accession Number 209033, FI117, seed comprising said FI117 transformation event having been deposited as ATCC Accession Number 209031, GG25, seed comprising said GG25 transformation event having been deposited as ATCC Accession Number 209032, and GJ11, seed comprising said GJ11 transformation event having been deposited as ATCC Accession Number 209030." The seeds of the specific transformation events are made available to the public at the American Type Culture Collection, or "ATCC," and the accession numbers identify where the seeds are indexed at the ATCC.

Because the parties have agreed to this construction, and because the construction appears consistent with the language of the claim, the Court adopts this construction in its entirety.

2. Application - Conception and Joint Inventorship

Conception has been called the "touchstone of inventorship." <u>Burroughs</u>

<u>Wellcome Co. v. Barr Labs., Inc.</u>, 40 F.3d 1223, 1228 (Fed. Cir. 1994). Courts have defined conception for the purposes of inventorship as:

'. . . the formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.' Hybertech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986) (quoting 1 Robinson on Patents 532 (1890)). An idea is sufficiently 'definite and permanent' when 'only ordinary skill would be necessary to reduce the invention to practice, without extensive research or experimentation.' Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d at 1228.

Ethicon Inc., 135 F.3d at 1460.

DeKalb contends that since the '497 patent is for the transformation events – i.e. the moment when the DNA cassette became fixed or inserted within the respective chromosomes of each of the four events – the RPA scientists could not be joint inventors because none of them could have had a definite and permanent idea of the complete and operative invention at the time of any contribution they may have made. The DNA inserts randomly, if at all, so no one could foretell prior to the event where an insertion point might be. (Spencer, Trial Tr. vol. VIII, 1101; Sailland, Trial Tr. vol. VIII, 1203.) Specifically, whether it would confer glyphosate resistance and to what extent could not be determined until testing. (Spencer, Trial Tr. vol. VIII, 1102-03.) Nor could the plant's fertility be immediately determined. Finally, DeKalb contends that in vitro resistance did not mean resistance for the whole plant and had never translated into sufficient resistance for a corn plant to withstand the amount of glyphosate recommended to kill weeds. (Lebrun, Trial Tr. vol. III, 535; Armstrong, Trial Tr. vol. III, 492.)

The short answer to DeKalb's contention is that, in the case of persons working jointly to solve a common problem as were the teams from RPA and DeKalb, different people may contribute in different ways and at different times toward a common conception. As the Federal Circuit observed in Fina Oil:

The issue of joint inventorship is governed by 35 U.S.C. § 116, which states, in relevant part:

When an invention is made by two or more persons jointly, they shall apply for a patent jointly and each make the required oath, except as otherwise provided in this title. Inventors may apply for a patent jointly even though (1) they did not physically work together or

at the same time, (2) each did not make the same type or amount of contribution, or (3) each did not make a contribution to the subject matter of every claim of the patent.

This provision sets no explicit lower limit on the quantum or quality of inventive contribution required for a person to qualify as a joint inventor. Rather, a joint invention is simply the product of a collaboration between two or more persons working together to solve the problem addressed. <u>Burroughs Wellcome</u>, 40 F.3d at 1227, 32 USPQ2d at 1919. The determination of whether a person is a joint inventor is fact specific, and no bright-line standard will suffice in every case.

Conception and inventorship are questions of law, reviewed de novo, that rest on underlying facts. *See* <u>Sewall</u>, 21 F.3d at 415, 30 USPQ2d at 1358.

Nonetheless, our precedent provides guidance as to what types of acts are, or are not, sufficient in quantum and quality to establish joint inventorship. One need not alone conceive of the entire invention, for this would obviate the concept of joint inventorship. However, a joint inventor must contribute in some significant manner to the conception of the invention. See Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 75 F.3d 1568, 1575, 37 USPQ2d 1626, 1632 (Fed. Cir.1996) (citing Sewall, 21 F.3d at 415, 30 USPQ2d at 1358-59). As such, "each inventor must contribute to the joint arrival at a definite and permanent idea of the invention as it will be used in practice." Burroughs Wellcome, 40 F.3d at 1229, 32 USPQ2d at 1921.

If a person supplies the required quantum of inventive contribution, that person does not lose his or her status as a joint inventor just because he or she used the services, ideas, and aid of others in the process of perfecting the invention. See Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir.1985). However, those others may also in appropriate circumstances become joint inventors by their contributions. In addition, a person is not precluded from being a joint inventor simply because his or her contribution to a collaborative effort is experimental. See Burroughs Wellcome, 40 F.3d at 1229, 32 USPQ2d at 1921.

The basic exercise of the normal skill expected of one skilled in the art, without an inventive act, also does not make one a joint inventor. See Sewall, 21 F.3d at 416, 30 USPQ2d at 1359. Therefore, a person will not be a co-inventor if he or she does no more than explain to the real inventors concepts that are well known and

the current state of the art. See Hess, 106 F.3d at 981, 41 USPQ2d at 1787. The case law thus indicates that to be a joint inventor, an individual must make a contribution to the conception of the claimed invention that is not insignificant in quality, when that contribution is measured against the dimension of the full invention.

123 F.3d at 1473.

In cases where conception does not occur until there has been a reduction to practice, a person who has contributed a significant, inventive act does not lose joint inventor status because the contribution was made prior to conception. As the Fina Oil court observed:

Conception and reduction to practice of the entire claimed invention may be relevant to establish that a first person conceived of an invention before another person entered the scene, and that the first person is therefore the sole inventor. However, the doctrine cannot be used, as the district court did here, to show that because the first person did not conceive or reduce to practice the entire claimed invention, he or she did not at least contribute in some significant way to the ultimate conception.

ld. at 1474.

The advisory jury found that each of the five RPA scientists should be named as inventors of the '497 patent. For the reasons which follow, the Court agrees with the advisory jury's determination.

The claim construction agreed upon by the parties comprises at least the following limitations: (1) A hybrid maize plant which (2) is resistant to glyphosate and which (3) contains a modified maize EPSPS gene encoding an EPSPS protein having Isoleucine at position 102 and Serine at position 106 in addition to (4) a promoter active in maize operably linked to the modified EPSPS gene. The plant

(5) must have as a parent one of the four specific transformation events: GA21, FI117, GG25, or GJ11.

The evidence clearly and convincingly shows that beginning in 1990, RPA and DeKalb engaged in a collaborative effort to create genetically engineered, glyphosate resistant corn. (Orozco, Trial Tr. vol. III, 473.) As observed earlier, each brought a special expertise to their project: RPA had an expertise in identifying and synthesizing DNA constructs which had the potential to lessen the binding of glyphosate in maize EPSPS enzymes and to permit the enzyme to continue its vital function in the plant's production of its own food. DeKalb had the transformation process of Drs. Lundquist and Walters and the consequent ability to bombard embryonic corn cells with RPA's genetic material and regenerate transformed plants containing that genetic material. The purpose of the collaboration was to create hybrid corn plants made glyphosate resistant by incorporating modified DNA encoding EPSPS enzymes which could perform the function of catalyzing the synthesis of EPSP in the presence of glyphosate.

Although RPA determined sometime in 1992 to suspend research efforts toward isolating new DNA constructs, it had already originated and synthesized maize DNA encoding a modified maize EPSPS protein with Isoleucine at 102 and Serine at 106 (the "DMMG"). It had identified and constructed several promoters operable in maize and, particularly active in the faster growing areas of the plant –

tips of stems and roots – where glyphosate concentrates most.²⁵ (Lebrun, Trial Tr. vol. III, 517-18.) And, RPA had originated and constructed the OTP which was more effective in delivering precursor EPSPS to the maize chloroplast, transporting the EPSPS across the membrane wall, and being cleaved at the precise site than any other transit peptide in the literature at that time. (Lebrun, Trial Tr. vol. III, 508-16.)

Pursuant to their agreement, in February 1993, RPA sent several constructs containing RD-125 (the DMMG with a Met and the OTP) linked to several promoters and other regulatory elements. It was those constructs which Michael Spencer of DeKalb used in the particle gun in the Spring and Summer of 1993 to create the transformation events claimed in the '497 patent. Those events, following selection, were tested in vitro for glyphosate resistance, regenerated into plants, tested in the laboratory, crossed with another line to create the R1 generation, then taken into the field for testing with glyphosate. (Spencer, Trial Tr. vol. VIII, 1104-20.)

After the testing of the plants in a greenhouse, on February 18, 1994, DeKalb reported the following to RPA:

[W]e have not only demonstrated that we can use the mutant maize EPSPS gene as a selectable marker in maize, but we have now

²⁵ One of these was the maize histone promoter which was "operably linked" to the DMMG in GG25. Another was the 35S/Arabidopsis histone promoter which was "operably linked" to the DMMG in GJ11. (PTX 1403 at DKB 039983.)

demonstrated tolerance in transgenic plants in the greenhouse to up to four times the field application recommended by Monsanto for tolerant corn! We will repeat these experiments in the field in the summer of 1994. It is obvious from these results that the mutant maize gene has been the key to success.

(PTX 240 at DKB 040277.)

During the subsequent field trials conducted in September 1994, each showed the ability not to be harmed from a 16 ounces per acre application of glyphosate – the recommended amount for killing weeds. GG25 (DMMG+OTP+maize histone promoter) and GJ11 (DMMG+OTP+35S/Arabidopsis histone promoter) appeared as healthy at 64 ounces per acre as plants which had not been sprayed at all. (Spencer, Trial Tr. vol. VIII, 1162; PTX 307 at DKB 040526.) At 64 ounces, FI17 (DMMG+OTP+rice actin promoter) became "somewhat yellow", a ranking of 2 on a scale in which 3 was "yellow, twisted", 4 was "wilted, stunted" and 5 was "dead". GA21 (DMMG+OTP+rice actin promoter)²⁶, at 64 ounces, graded 2.5. (PTX 307 at DKB 040526.)

At that point conception was complete: hybrid plants – the offspring of two different genotypes, one parent of each being one of the four claimed transformation events, each containing a DNA cassette with a modified maize EPSPS gene encoding an EPSPS protein having Isoleucine at position 102 and Serine at position 106, and a promoter active in maize operably linked to the

²⁶ Although F117 and GA21 have the same constructs (DMMG+OTP+rice actin promoter) they are different transformation events; the DNA inserts randomly.

modified EPSPS gene – had demonstrated glyphosate resistance.

It is true that conception was completed without RPA or any of its scientists being informed of the successful field trials. DeKalb's proceeding with further testing and crossing with elite lines to commercialize "Roundup Ready®" corn without informing RPA was the subject of a previous jury finding that DeKalb had committed fraud, breached the collaboration agreement, and been unjustly enriched. See Rhone-Poulenc Agro, S.A. v. DeKalb Genetics Corp., 272 F.3d 1335 (Fed. Cir. 2001) (vacated and remanded for reconsideration of the amount of punitive damages in light of State Farm Mut. Auto Ins. v. Campbell, 538 U.S. 408, 123 S. Ct. 1513 (2003) by DeKalb Genetics Corp. v. Bayer CropScience, S.A., 538 U.S. 974, 123 S. Ct. 1828 (2003), opinion modified and reinstated by Rhone-Poulenc Agro, S.A. v. DeKalb Genetics Corp., 345 F.3d 1366 (Fed. Cir. 2003), cert. denied, DeKalb Genetics Corp. v. Bayer CropScience, S.A., 540 U.S. 1183, 124 S. Ct. 1423 (2004)). That, however, is a non-issue since neither the statute nor the cases relating to joint inventorship requires the simultaneous presence or awareness of all who have contributed significantly toward conception when the last piece of the conception puzzle slips into place.

It is beyond serious question that RPA scientists contributed genetic constructs which, when inserted, created the glyphosate resistance possessed by each of the transformation events. It is undisputed that RPA scientists provided the "modified maize EPSPS gene encoding an EPSPS protein having [I]soleucine at

position 102 and [S]erine at position 106" as well as two "promoter(s) operably linked to said EPSPS gene" claimed in the '497 patent. (PTX 142 at DKB 040519; Spencer, Trial Tr. vol. VIII, 1127, 1139.) DeKalb argues, however, that none of the RPA scientists made a contribution of inventive significance, but rather were merely explaining and practicing the state of the art. Thus, the next step is a consideration of the specific contributions of each of the five and a determination of whether that person made an inventive contribution which was not insignificant when measured against the dimension of the full invention.

Dr. Georges Freyssinet was the RPA glyphosate resistance project leader.

Dr. Freyssinet attended the Scientific Committee meetings with both Calgene and DeKalb where attendees discussed ideas and research plans for improving resistance. In 1989, at a Scientific Committee meeting with Calgene, Dr. Comai discussed the possibility of mutating a wild type bacterial EPSPS gene by combining the Pro÷Ser, 101, mutation from the CT7 aroA gene with the Threo÷Iso, 97, mutation from the B808 randomly mutated bacterial gene.

(Comai, Trial Tr. vol. v, 863-68; DTX 1477 at RPA 031675, 031685.) At the meeting, Dr. Freyssinet proposed that RPA would mutate a maize gene. (Comai Trial Tr. vol V, 893; DTX 1477 at RPA 031676.)²⁷

Although using plant genes for mutagenesis had been discussed from time to time within Calgene and debated within the Scientific Committee meetings with

²⁷ (See also PTX 1429.)

RPA, Dr. Comai never made a concrete proposal to do so, electing instead to continue research with the Salmonella gene. (Comai, Trial Tr. vol. V, 877, 879-81, 888, 889.) It was later determined that the Threo÷Iso, 97, mutation was toxic to the mutagenized bacteria and Calgene never performed the site directed mutagenesis to encode both the Threo÷Iso, 97 and the Pro÷Ser, 101 substitutions in a single aroA gene. (Freyssinet, Trial Tr. vol IV, 619-21; PTX 1431 at CAL 004228-004246; Lebrun Trial Tr. vol. IV, 573.) Further, transformed tobacco plants with the Threo÷Iso, 97 substitution had underdeveloped roots, leading to the conclusion that the protein was not stable. (Freyssinet, Trial Tr. vol. IV, 621-22.)

At RPA in 1986, a focus had been on increasing glyphosate resistance in maize by developing a line that produced an overabundance of EPSPS enzymes. The cells of this line were more tolerant than wild type maize. In 1989 it was decided by the project team – Drs. Freyssinet, Lebrun, Leroux and Sailland – to use cells preserved from this line for site directed mutagenesis. Starting in late 1989, Michel Lebrun spent about one year isolating the EPSPS gene from the cDNA. (Freyssinet, Trial Tr. vol. IV, 613, 626-28.) The gene was then sequenced and it was determined that there were three nucleotide and three amino acid changes from that published by Monsanto in 1988. (Lebrun, Trial Tr. vol. III, 563-64; DTX 1620 at RPA 016933.) At a meeting in Lyon, a decision was made by the four team members to combine, two by two, the Threo÷lso, Pro÷Ser, and Gly÷Ala

mutations in the conserved region around amino acid position 100. They decided to start by making eight variants, one with the specific mutations resulting in Threo÷Iso, 102, and Pro÷Ser, 106 (the "DMMG"), even though the Threo÷Iso substitution had proven toxic when made in bacteria. They also decided to make a single mutation resulting in a Gly÷Ala, at position 101 and another single mutation with a Pro÷Ser at position 106. (Freyssinet, Trial Tr. vol. IV, 627; Lebrun, Trial Tr. vol. IV, 572, 573; DTX 1944 at RPA 008138.)

It was, therefore, the idea of Drs. Freyssinet, Lebrun, Sailland and Leroux to combine the mutations resulting in Threo÷Iso, 102, and Pro÷Ser, 106, in a maize cell. While Monsanto had mutagenized a maize gene, made hundreds of thousands of mutations in EPSPS genes, and a number of changes in the 101, 102, 105 and 106 region of plant genes, it had never combined the Threo÷Iso, 102, and Pro÷Ser, 106. (Padgette, Trial Tr. vol. IV, 581, 584-85.) While Dr. Comai had broached, both during and prior to the collaboration with RPA, the advisability of using plant genes, the possibility had never matured beyond debate. Also, while Dr. Comai had suggested the combination in bacteria of Threo÷Iso, 97, and Pro÷Ser, 101 – the equivalent amino acid positions in *Salmonella* to 102 and 106 in maize, the combination was not made after it was determined that the substitution of Isoleucine at position 97 had a toxic effect on the host bacteria.

The DMMG was essential to glyphosate resistance in each of the transformation events: it had the physical structure to block the glyphosate

molecule while allowing entrance of the PEP, resulting in an EPSPS enzyme able to perform its life sustaining function in the presence of considerable amounts of glyphosate.

Drs. Freyssinet, Leroux and DeRose originated and synthesized the maize histone promoter which was "operably linked" to the DMMG in GG25. Dr. Freyssinet and Dr. Leroux also originated and synthesized the 35S/Arabidopsis histone promoter which was "operably linked" to the DMMG in GJ11. The promoter controls the transcription phase by attracting the RNA polymerase and it also directs where in the plant the gene will be expressed. It was important to have a promoter that would produce a lot of EPSPS, especially in the areas of the corn plant where glyphosate accumulates – tips of stems and roots. (Lebrun, Trial Tr. vol. III, 516-18; DeRose, Trial Tr. vol. I, 141-42, 146.)

Drs. Lebrun, Leroux and Sailland originated and synthesized the OTP, the "optimized transit peptide", which targets the chloroplast for the EPSPS precursor protein and accomplishes entry through the chloroplast wall before being cleaved from what then becomes the mature EPSPS protein or enzyme. DeKalb contends that the OTP was a prior art element and should not be considered an inventive contribution to these transformation events. The OTP, however, had been sent to DeKalb in 1991 as an integral portion of a construct (with the 35S/Arabidopsis histone promoter and the CT7) as a part of the RPA/DeKalb joint effort toward creating glyphosate resistant corn. (PTX 53 at DKB 009830.) And, Dr. Lebrun

had discussed the OTP with DeKalb scientists at a Scientific Committee meeting in October, 1991. (PTX 55 at DKB 026454; Lebrun Trial Tr. vol. III, 519.) While Drs. Leroux, Lebrun and Sailland applied for a French patent on the OTP in March of 1991, the OTP was not disclosed to the public until September 11, 1992. (DTX 1257.) Because they were the inventors and were working collaboratively with DeKalb, they would not have been simply explaining prior art when the OTP was sent to DeKalb with the DMMG in February, 1993. In re Katz, 687 F.2d 450 (CCPA 1982); see also Pannu, 155 F.3d at 1344 (holding Pannu was at least a coinventor because he and the other purported inventor had worked collaboratively and Pannu had conceived of significant aspects of the invention although he had discussed his ideas with others more than a year earlier than he did with the other purported inventor).

Considering the extensive but unavailing efforts of other researchers in the field to modify DNA and alter the structure of the EPSPS enzyme so that it would block the glyphosate molecule, yet allow the PEP to bond with the shikimate and form EPSP, there is no doubt that the RPA constructs were the most significant genetic development in the effort to create glyphosate resistant maize. It is determined that each of the contributions enumerated above are inventive and significant when compared to the invention as a whole. Each was vital to the creation of glyphosate resistance in at least one of the four transformation events and each of the five individual RPA scientists should be added as co-inventors on

the '497 patent.

It is further determined, however, that the following contributions cited by RPA do not rise to the level of inventive significance.

Dr. Freyssinet's informing DeKalb at the first Scientific Committee meeting in June, 1991 about the probable efficacy of the rice actin promoter in maize, (see DTX 290 at DKB 026532), was an explanation of the state of the art, not an inventive contribution. See Hess v. Advanced Cardiovascular Sys. Inc., 106 F.3d 976, 981 (Fed. Cir. 1997).

Dr. DeRose's addition of the Met to the OTP-DMMG junction and his modification of the OTP by adding restrictor sites for easier addition or removal of promoters certainly contributed to the probable effectiveness of the constructs but constituted practicing the state of the art. There is no showing that either were inventive contributions. As he testified, the literature at the time reported the effectiveness of a Methionine in prolonging the stability of proteins. (DeRose, Trial Tr. vol. II, 222-23.) There is no evidence to support a finding by clear and convincing evidence that adding restrictor sites was novel and there was evidence that it was not. (Spencer, Trial Tr. vol. VIII, 1137-38.)

Nor does the evidence support a finding of an inventive aspect in Dr.

DeRose's combination of elements for the various constructs sent in February,

1993. According to his testimony, the ideas for combining OTP with the DMMG and, then, with different promoters were attributable variously to Drs. Freyssinet,

Lebrun, Leroux and Sailland. (DeRose, Trial Tr. vol. II, 221, 222, 226.)

Similarly, while Dr. Lebrun's contribution of isolating the maize EPSPS gene was central to obtaining the DNA to be mutagenized, there is no showing that it was more than a state of the art undertaking.

B. The '798 patent

1. Claim Construction

The second patent for which RPA seeks to have its five scientists declared joint inventors is the '798 patent. Claim 1 of the '798 patent reads:

A fertile transgenic *Zea mays* plant containing an isolated heterologous DNA construct encoding EPSP synthase wherein said DNA construct is expressed so that the plant exhibits resistance to normally toxic levels of glyphosate, wherein said resistance is not present in a *Zea mays* plant not containing said DNA construct, and wherein said DNA construct is transmitted through a complete normal sexual cycle of the transgenic plant to the progeny generation.

('798 Patent, col.26, II.15-23.) The parties stipulated to all of the claim construction except as to how to construe the following language in the claim: "the plant exhibits resistance to normally toxic levels of glyphosate, wherein said resistance is not present in a *Zea mays* plant not containing said DNA construct." The Court ultimately construed that language and instructed the advisory jury that the terms effectively meant that an amount of glyphosate normally sufficient to kill a non-transgenic corn plant would have no effect upon the transgenic plant. This, then, was construed as the transformed plant having total resistance or immunity to an amount of glyphosate which would normally kill non-transgenic corn. The

advisory jury found that the five RPA scientists had contributed to the conception of: 1) fertile transgenic corn containing DNA constructs encoding non-bacterial mutated plant EPSP synthases; and 2) fertile transgenic corn containing DNA constructs encoding EPSP synthases that provide glyphosate resistance to corn.

After further consideration, the Court believes it improperly construed the claim at issue and, therefore, improperly instructed the advisory jury. This section discusses the construction read to the jury, the construction now adopted, the basis for the Court's interpretations and the effect on the claims of the plaintiffs to be added as inventors on the '798 patent.²⁸

a.

The procedure for claim construction is well known. The first step is an examination of the intrinsic evidence which includes: (1) the language of the claims themselves; (2) the patent's specification; and (3) the patent's prosecution history. Markman, 52 F.3d at 979. This intrinsic evidence is the "most significant source of the legally operative meaning of the disputed claim language." Vitronics

Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996).

Thus, a district court should "[f]irst . . . look to the words of the claims themselves, both asserted and nonasserted, to define the scope of the patented

²⁸ Because the jury empaneled in this case was advisory, the district court is ultimately responsible for the findings of fact and conclusions of law. See In re Incident Aboard D/B Ocean King v. Ocean Drilling and Exploration Co., 758 F.2d 1063, 1071 (5th Cir. 1985) ("[A]ny errors relating to rulings before the [advisory] jury and instructions to the [advisory] jury need not be considered.") (citing cases).

invention." Id. The court is then to look to the specification of the patent which contains a written description of the invention which must be clear and complete enough to enable those of ordinary skill in the art to make and use the invention. ld. Finally, the prosecution history, often referred to as the "file wrapper," should be considered by the court. Id. The prosecution history contains the complete record of all of the proceedings before the Patent and Trademark Office. The prosecution history is often of "critical signification in determining the meaning of the claim" because it includes any express representations made by the applicant regarding the scope of the claims. Id.; see also Southwall Tech. Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during the prosecution.") (citations omitted). However, "[a]Ithough the prosecution history can and should be used to understand the language used in the claims, it . . . cannot 'enlarge, diminish, or vary' the limitations in the claims." Markman, 52 F.3d at 980 (quoting Goodyear Dental Vulcanite Co. v. Davis, 102 U.S. 222, 227 (1880)).

When the intrinsic evidence fails to resolve the ambiguity in the disputed term, extrinsic evidence may be considered. See, e.g., Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1216 (Fed. Cir. 1995) ("Extrinsic evidence may also be considered, if needed to assist in determining the meaning or scope of technical terms in the claims.") (citations omitted, emphasis added); Vitronics

Corp., 90 F.3d. at 1583 (explaining that it is only proper to rely on extrinsic evidence if the analysis of the intrinsic evidence fails to resolve the ambiguity in the disputed claim term). Extrinsic evidence includes evidence outside of the patent and its prosecution history, such as expert testimony, the inventor's testimony, dictionaries, and learned treatises. Markman, 52 F.3d at 980-81 (suggesting this is not an exhaustive list and that any evidence that is helpful may be admitted as extrinsic evidence). However, if this evidence is necessary, it can only be used by the court to aid its understanding of the patent, and not to vary or contradict the terms as used in the claims. See id. at 981; Vitronics Corp., 90 F.3d at 1583 ("Allowing the public record to be altered or changed by extrinsic evidence introduced at trial, such as expert testimony, would make [the public's right to rely on the public record] meaningless"); Southwall, 54 F.3d at 1578 ("A patentee may not proffer an interpretation for the purposes of litigation that would alter the indisputable public record consisting of the claims, the specification and the prosecution history ").

Finally, if extrinsic evidence does not resolve the ambiguity, there are various canons of construction that can be used to arrive at an interpretation. See, e.g., Katz v. AT&T Corp., 63 F. Supp. 2d 583, 589 (E.D. Pa. 1999) ("To complete the task of claim construction, a court may draw on the canons of construction that can be sifted from the decisions of the Court of Appeals for the Federal Circuit spanning before Markman and beyond."); 5A Chisum on Patents, § 18.03 [2][a]

(citing examples of canons commonly used in construing patent claims).

b.

The first disagreement by the parties centers around the meaning of the word "resistance". RPA argues that "resistance" means something like immunity; that a non-transgenic plant would die from application of a normally lethal amount of glyphosate while the transgenic plant would remain unharmed (the construction given the advisory jury). DeKalb, on the other hand, contends that "resistance" is inherently comparative; that a plant exhibits "resistance" to glyphosate if it suffers even slightly less harm from an application of glyphosate than do normal corn plants.

The starting point, then, is an examination of the intrinsic evidence, here the patent claim language, the specification, and the prosecution history. RPA points to the prosecution history where the terms "resistance" and "partial resistance" each appear. (Pros. Hist. '798 Patent at 804²⁹, 812³⁰.) RPA argues that the

²⁹ In an Interview Summary dated May 24, 1996, the patent examiner states: "The declaration clearly evidences that a person of ordinary skill in the art, employing the methods disclosed in the specification, would have obtained a transgenic corn plant expressing EPSP synthase at levels sufficient to obtain resistance or partial resistance to glyphosate at leaves that would normally kill corn." (Pros. Hist. '798 Patent at 804 (emphasis added).)

³⁰ T. Michael Spencer, a DeKalb scientist, filed a Declaration dated August 12, 1993 in which he provided information about two examples of experiments. (See Pros. Hist. '798 Patent at 807-15.) Example One discussed experiments with versions of the aroA gene in which Spencer concluded that "a low level of expression of the aroA gene had been attained which provides partial resistance to herbicide application." (Pros. Hist. '798 Patent at 812 (emphasis added).) In

concept of "partial resistance" would have no meaning unless "resistance" were interpreted as complete or absolute resistance. See Phillips v. AWH Corp., 415 F.3d 1303, 1314 (Fed. Cir. 2005) (explaining that the term "steel baffles" strongly implies that the term "baffles" does not inherently mean objects made of steel); Minebea Co. v. Think Outside, Inc., 159 Fed. Appx. 197, 202 (Fed. Cir. 2006) (explaining that because the claim provides that certain structures will "slide in addition to pivot" sliding motion should not be subsumed into pivoting motion).

However, after reviewing the specification, the prosecution history, and the arguments of counsel, it is determined that the intrinsic evidence substantially supports DeKalb's view that, as used in claim 1, "resistance" should be accorded its broader meaning, i.e. that a transgenic plant is "herbicide resistant" even if it is severely harmed by herbicides, so long as it is less harmed than the non-transgenic version of the plant would be at the same applied level of glyphosate.

For example, the specification – which does not describe a transformation in which glyphosate resistance was the trait being conferred – does describe a transformation which used the process claimed in the original application for conferring a trait for hygromycin resistance and also describes the testing for evidence that the DNA encoding hygromycin resistance had been inserted and passed to the R1 generation. In the test, the tissue was subjected to hygromycin

contrast, Example Two, which discussed experiments with the mutant maize ESPS gene, concluded that <u>glyphosate resistance</u> had been conferred. (Pros. Hist. '798 Patent at 815 (emphasis added).)

and then scored from 0 to 6; 0 being all brown and 6 being all green. ('798 Patent, col.21, II.6-12.) Those scoring from 3 to 6 were classified as "hygromycin resistant". ('798 Patent, col.21, II.6-12.) Significantly, the tissue scored at 3, 4, and 5 – each being classified as "resistant" – would be less than all green with a 3 being more brown than green. Thus, the specification itself ascribes a meaning to the term "resistance" much broader than total resistance or immunity.

Additionally, the prosecution history contains several statements by DeKalb through its attorneys which suggest the understanding of "resistance" intended in the application. First, the prosecution history contains a reference by DeKalb's patent attorney to a declaration by T. Michael Spencer, one of DeKalb's scientists. (Pros. Hist. '798 Patent at 416.) The attorney contends that the declaration shows that "resistance to glyphosate" has been imparted to corn plants. Read together with the declaration itself which discusses the production of transgenic corn plants that are severely harmed by glyphosate, though somewhat less so that normal corn plants, it is clear that the attorney is using the term "resistance" in a broad sense.³¹ (Pros. Hist. '798 Patent at 807-15.)

Second, the Amendment filed by DeKalb's attorneys on February 22, 1996³², contains a description of resistance that strongly suggests inclusion of

³¹ The same sense in which clothing that is not waterproof is sometimes called "water resistant."

³² The Amendment was sent February 19, 1996, but does not appear to have been filed until several days later.

more than just immunity. That Amendment states: "The DNA construct is expressed so that the transgenic plant exhibits tolerance or resistance to glyphosate at levels that render it identifiable over the corresponding untransformed corn plant which does not comprise the heterologous DNA." (Pros. Hist. '798 Patent at 748-49.) The DeKalb attorney's statement conveys an understanding of resistance that includes the transgenic plant being harmed, but less so than the non-transgenic corn, and not that of immunity.

Such statements, made by the patent applicant himself, are strong evidence of the meaning intended in the claim language. See Markman, 52 F.3d at 980 ("Th[e] construction of the patent is confirmed by the avowed understanding of the patentee, expressed by him, or on his behalf, when his application for the original patent was pending [W]hen a patent bears on its face a particular construction, inasmuch as the specification and claim are in the words of the patentee, . . . such construction may be confirmed by what the patentee said when he was making his application.") (citing Goodyear Dental, 102 U.S. at 227).

There is no suggestion in the prosecution history that DeKalb, in its communications with the Patent Office, ever agreed to or was asked to limit the meaning of resistance to full or total resistance. In this context, it is interesting to note that the cited use of the phrase "resistance or partial resistance" was that of the patent examiner who at the time was necessarily using both as fulfilling the limitation of "resistance" in claim 1. The patent examiner's Interview Summary

dated May 24, 1996 contains the following statement:

The specification does not clearly evidence the effects of the expression of EPSP synthase in transgenic corn plants in the absence of [sic] Spencer declaration, the orginal [sic] filed in parent application 07/508,045, of the instant continuation application. Applicants' attorney submitted said declaration for review in this interview. The declaration clearly evidences that a person of ordinary skill in the art, employing the methods disclosed in the specification, would have obtained a transgenic corn plan expressing EPSP synthase at levels sufficient to obtain resistance or partial resistance to glyphosate at levels that would normally kill corn Actual reduction to practice is viewed as the completion of the conception of the invention (Fiers v. Sugano 25 USPQ2d 1601 (Fed Cir. 1993)).

(Pros. Hist. '798 Patent at 804 (emphasis added).) As is evident from this statement, the patent examiner put great weight in the information contained in the Spencer declaration. The Spencer declaration described one example of a transformation in which Comai's CT7, aroA bacterial gene, was biolistically implanted into embryonic cells, a plant regenerated and crossed with a non-transgenic plant. Plants of the R1 generation were then subjected to applications of 2, 4, 8 and 16 ounces of glyphosate. At the two ounce level, all lived; at the eight and sixteen ounce levels all died. At the four ounce level some died and those that lived were stunted. The example was cited in the declaration as illustrating that "a low level of expression of the aroA gene had been attained which provides partial resistance to herbicide application." (Pros. Hist. '798 Patent at 811-12 (emphasis added).) Example Two described transformation using RPA's construct of the DMMG and the OTP constructs, but only through the in vitro stage. Following microprojectile bombardment and a selection process in which

glyphosate was used in the growth medium as a selectable marker, Southern blot hybridization showed that both callus lines tested had incorporated the new DNA. This was cited in the Spencer Declaration as a clear demonstration of the "introduction and expression in cultured maize cells and plants of an ESPS gene which confers glyphosate resistance." (Pros. Hist. '798 Patent at 815 (emphasis added).) The use of the term "glyphosate resistance" in the second example describing the in vitro analysis of a cell line and not a plant was not inconsistent with the use of the term "partial resistance" as it was applied to the testing of a fertile, transgenic plant of the R1 generation in the first example. Both were consistent with the use accorded the term "resistant" in the specification when "hygromycin resistant" tissue was defined to include all shoots scoring from 3 to 6 after being exposed to hygromycin. ('798 Patent, col.21, II.5-13.)

С.

This, however, does not completely define the key phrase in question: "exhibits resistance to normally toxic levels of glyphosate." In addition to an interpretation of what "resistance" means, it is also necessary to construe the second part of this phrase, specifically what levels of glyphosate would be "normally toxic".

When construing patent claims, the Court does not presume any of the words of the claim to be superfluous. See Elekta Instruments S.A. v. O.U.R.

Scientific Int'l, Inc., 214 F.3d 1302, 1307 (Fed. Cir. 2000). Therefore, the words

"toxic" and the word "normally" must both be given a meaning. Both parties agree that "normally toxic" should be interpreted broadly as a differential and not a specific level or amount of glyphosate. However, the question remains as to whether "normally toxic" requires that the non-transgenic corn plant is killed or merely harmed by the application of the glyphosate.

The plain meaning of "toxic" suggests something less is required than the plant actually being killed. Rather, the word "toxic" is generally equated with the word "poison". See Webster's New Universal Unabridged Dictionary 2003 (defining "toxic" as "acting as or having the effect of a poison; poisonous"). "Poison", however, is defined in the following manner, "a substance with an inherent property that tends to destroy life or impair health." Id. at 1495. Thus, the word "toxic" likely covers both harm to the plant, as well as death to the plant.

This definition of "toxic" is supported by the patent specification as well. In column 12 the specification uses the word "toxic" in a way that suggests that something can be "toxic" at varying levels. ('798 Patent, col.12, II.7-25.) For example, the specification discusses exposure to a toxic agent first at a "relatively low toxic agent concentration" which should result in "about a 5-40% level of growth inhibition . . ." ('798 Patent, col.12, II.11-18.) It then discusses exposure

³³ The parties disagree regarding what the differential should be: DeKalb arguing that it should be the amount that would effectively kill a plant (Hr'g Tr. 54, Aug. 31, 2000), and RPA arguing it should be the amount that would harm a plant (Hr'g Tr. 55, Aug. 31, 2000.)

of a toxic agent at a higher concentration to "kill essentially all untransformed cells" and resulting in a "30 to 100% growth inhibition." ('798 Patent, col.12, II.23-29.) Thus, although not referring directly to the process described in claim 1, the specification clearly uses the word toxic to mean harming as well as killing the subject of the application. Applied to the application of glyphosate to non-transgenic corn, as described in claim 1, toxic would refer to an amount of glyphosate that would harm or make sick the non-transgenic corn plant.³⁴

In this case "normally" refers to the amount of the glyphosate that would cause this harm, but it likely does not mean any amount of glyphosate conceivable. Rather "normally" in this sense logically correlates to the amount of glyphosate that would, if applied, at least make the non-transgenic corn plants sick or have some other adverse affect. Thus, the term "normally" should be construed as the amount of glyphosate that, under similar circumstances, is usually enough to adversely affect or harm a non-transgenic corn plant. This construction addresses DeKalb's concerns that the amount of glyphosate that is normally applied varies depending on the geographic location of the plants, the stage of growth at which the glyphosate is applied, and other factors that may affect the amount that would

³⁴ The patent examiner, however, makes a comment in the patent history on May 24, 1996, that is contrary to this construction. (Pros. Hist. '798 Patent at 804) (stating that the invention had been reduced to practice based in part on the ability to obtain resistance or partial resistance at "levels that would normally *kill* corn") (emphasis added). However, because the patent history is not to be used to "enlarge, diminish, or vary the limitations in the claims," the patent examiner's comments are not instructive. <u>Markman</u>, 52 F.3d at 980 (citations omitted).

harm a plant.

However, given the meaning accorded the word "resistance" in section (b), supra, whether "normally toxic" refers to a lethal or non-lethal application of glyphosate is of no consequence in determining whether any of the five applicants in this case should be added as inventors.

2. Application - Conception and Joint Inventorship

According to the Prosecution History, the examiner accepted the Spencer Declaration, necessarily Example One, as evidencing a reduction to practice of the limitations contained in claim 1. Example One described April 1993 field testing of fertile transgenic plants of the R1 generation containing DNA constructs with Dr. Comai's CT7, aroA, bacterial EPSPS gene. As discussed earlier, plants were sprayed with glyphosate applications of 2, 4, 8 and 16 ounces per acre. According to DeKalb's May 10, 1993 research report:

All plants were killed in the 8oz. and 16 oz. treatments. These are the lowest rates currently recommended by Monsanto for easy to control weeds. Greg Parker estimates that the recommended rate of control of weeds in transgenic corn may be 16 oz/A. The 2oz rate did not kill any plants, but their size and rate of growth were stunted. The 4oz rate killed some of the plants, while the growth of others were severely stunted. The ratio of dead plants to slow growing plants was 3:1.

(PTX166 at DKB 056731.)

Thus, in April 1993, DeKalb researchers had established through transformation, regeneration and crosses:

[a] fertile transgenic *Zea mays* plant containing an isolated heterologous DNA construct encoding EPSP synthase wherein said

DNA construct is expressed so that the plant exhibits resistance to normally toxic levels of glyphosate wherein said resistance is not present in a *Zea mays* plant not containing said DNA construct, and wherein said DNA construct is transmitted through a complete normal sexual cycle of the transgenic plant to the progeny generation.

('798 Patent, col.26, II.15-23.)

Conception could have occurred no later than an actual reduction to practice, April 1993. This was at a time when the RPA constructs were becoming the new focus of DeKalb's glyphosate resistance research, following initial microprojectile bombardment and selection, but before any plants had been regenerated. (PTX166 at DKB 056726-28). Insofar as the '798 patent is concerned, conception had occurred prior to the making of significant inventive contributions by the RPA scientists. Without further research, i.e. regeneration, crossing and testing, the idea that the trait of glyphosate resistance could be conferred to fertile transgenic maize plants with constructs containing the DMMG or DMMG and OTP was theoretical. There was no evidence that RPA had actually tested the efficacy of constructs containing the DMMG or DMMG and OTP before - or after - sending them to DeKalb. It was unknown in April 1993 whether the shape of the maize EPSPS coil, altered by replacement of Serine for Proline at position 102 and Isoluceine for Threonine at position 106 would disrupt the bonding of glyphosate in a plant; experience in the art had shown that what worked in the test tube or petri dish often did not work in the plant. And since the point of actual insertion of DNA within the genome was random and could well be determinative of the gene's

expression and even the plant's subsequent fertility, a conception which included the DMMG or DMMG and OTP (RPA's contributions) could not have occurred until after April 1993. See Fiers, 984 F.2d at 1168-69.

Because conception had occurred prior to any of the applicants making a significant inventive contribution, the applications of the RPA scientists to be added as joint inventors to the '798 patent shall be denied.

IV. EQUITABLE ESTOPPEL

Despite the above reasons for adding the RPA scientists as inventors to the '497 patent, DeKalb argues that communications between RPA and DeKalb during the time of DeKalb's successes with the DMMG show that RPA should be equitably estopped from asserting joint inventorship. Specifically, DeKalb contends that the letters exchanged between it and RPA in the fall of 1993 form the basis for equitable estoppel in this case because the communications notified RPA that DeKalb was writing the patents. The facts surrounding these exchanges and the application of the doctrine of equitable estoppel will be discussed in turn below.

Α.

Throughout 1993, Dr. DeRose at RPA kept in contact with the scientists

from DeKalb, including Michael Spencer³⁵ and Dr. Chris Flick.³⁶ Dr. DeRose visited DeKalb's lab in August of 1993 and toured the laboratory and greenhouses.

(DeRose, Trial Tr, vol. I, 173-74.) Moreover, in 1993 and 1994, DeKalb kept RPA informed about various early phases of testing the constructs, and asked for RPA's permission to use the DMMG or the DMMG and OTP (RD-125) as a selectable marker in transformations with other genetic material.

The initial communication of the exchanges between DeKalb and RPA was on August 5, 1993 when Douglas Fisher, Deputy General Counsel of DeKalb, wrote to John Power of RPA about several matters. The portion pertinent to this inquiry, with emphasis added, reads as follows:

August 5, 1993

Mr. John Power Clause, S.A. 1, Avenue Lucien Clause 91221 Bretigny Sur Orge Cedex FRANCE

VIA FACSIMILE

Dear John:

I will be out August 2-5. Here are some items I want you to consider:

1. RPA Genes. Attached is a copy of a declaration we intend to file this week in the U.S. Patent Office in support of our corn transformation patent. Similar information would be in the application.

³⁵ Spencer was hired by DeKalb to work on corn transformation and is the named inventor on the '497 patent.

³⁶ Dr. Flick also worked for DeKalb on corn transformation and was Spencer's supervisor during the collaboration with RPA.

The genes referred to were obtained by us from RPA and RPA designed the mutations. This information would be confidential until any patent issues, which is not in the immediate future

Sincerely,

Douglas A. Fisher
Deputy General Counsel

tkr

cc: Chris Flick Catherine Mackey Tom Rice John Witmer

(DTX 595 at RPA 024235-36 (emphasis added).)

The ten page document which, with insubstantial changes, was filed with the Patent Office as the "Spencer Declaration" stated that: glyphosate is an effective herbicide for post emergence control of weeds in corn production, that corn itself lacks resistance to glyphosate, that development of novel corn lines possessing "glyphosate-resistance genes" is made possible by employing corn transformation methods and that "glyphosate-resistance genes" may also be employed as selectable markers³⁷ for identification of transformed plants and cell lines. (DTX 595 at RPA 024239-48.) The declaration continued:

³⁷As described earlier, the DMMG when attached to other genetic material was usable as a selectable marker to demonstrate which transformed cells had incorporated the new DNA. Following the transformation procedure, all embryonic cells bombarded by the microprojectiles coated with the new DNA would be placed on a medium containing glyphosate. Those which lived would have necessarily incorporated the new DNA somewhere within their chromosomes. DeKalb had never been successful in using the aroA gene as a selectable marker because it did not provide sufficient tolerance to glyphosate. (PTX 166 at DKB 056725.)

Glyphosate inhibits the action of the enzyme EPSP-synthase which is active in the aromatic amino acid biosynthetic pathway. Inhibition of this enzyme leads to starvation for the amino acids phenylalanine, tyrosine, and tryptophan and secondary metabolites derived thereof. U.S. Patent 4,535,060 describes mutations of the EPSP-synthase encoding gene of *Salmonella typhimurium* (aroA) which confer resistance to glyphosate. The EPSP-synthase gene was also cloned from *Zea mays* and mutations similar to those found in a glyphosate resistant aroA gene were introduced in vitro. Two examples are described below of the introduction of these genes into corn to confer glyphosate resistance. In the second example the gene is employed as a selectable marker.

(DTX 595 at RPA 024239 (underline emphasis added).)

The text of Example One discusses DeKalb's efforts at transforming corn cells with the aroA (CT7), growing the cells into a mature plant which was crossed with a non-transformed inbred plant, and developing kernels from which embryos were isolated and cultured until plants developed. The declaration text describes how resulting offspring were field tested with applications of two, four, eight and sixteen ounces of glyphosate per acre and states: "All plants were killed in the 8 oz and 16 oz treatments (normal field application rates for weed control). At 4 oz/A a portion of the transformed plants were killed and a portion were stunted in growth. The ratio of dead plants to slow growing plants was 3:1 (Table 14) indicating that there was a low level of expression of the aroA gene providing partial resistance to herbicide application." (DTX 595 at RPA 024242.)

Example Two discusses transformation studies "conducted using two mutant maize EPSP-synthase genes," the RPA constructs. (DTX 595 at RPA 024243; PTX166 at DKB 056726.) The text discusses using various combinations of the

two mutant maize genes with different promoters to bombard corn cells, the growing of the resultant transformed cells using glyphosate as the selection agent, and the use of Southern blot tests to confirm that the mutant maize genes had been introduced into the corn plant cells. The text concludes with the paragraph:

The above two examples clearly demonstrate the introduction and expression in cultured maize cells of EPSP-synthase genes conferring glyphosate resistance. Moreover, glyphosate was successfully used as the selection agent for identification of the transformed cell lines. Regeneration of plants from the transformed cell lines is in progress.

(DTX 595 at RPA 024248.)

Apparently RPA did not respond before Dr. Catherine Mackey wrote to Dr. Freyssinet of RPA on August 12, 1993. Dr. Mackey reiterated the information in the August 5 letter noting that "In the course of prosecution of one of our corn transformation patent applications, we have been asked by the examiner to provide evidence of expression of various transgenes in corn Since this [declaration] contains confidential information of Rhone-Poulenc, your permission is requested to include this information in the declaration." (DTX 599 at RPA 020678 (emphasis added).) The letter attached an insubstantially different draft of the declaration.

The next day, DeKalb wrote to RPA to clarify some information conveyed in the previous day's correspondence. (DTX 608 at RPA 020684.) DeKalb again referenced its "corn transformation patents" and stated that it did not see any reason why RPA "would be concerned about the disclosure of this information to the US Patent Office" but noted that it needed RPA's permission to disclose the

information under the Confidentiality Agreement. (DTX 608 at RPA 020684.)

A few days later, Dr. Freyssinet responded, granting permission for DeKalb to use RPA's constructs "to examplify [sic] your patent on corn transformation" with some conditions. (DTX 617 at DKB 017134.) One of those conditions was that DeKalb would provide similar information to support RPA's patents on promoters.

On September 27, Dr. Freyssinet wrote to Dr. Mackey requesting information about DeKalb's results using RPA's genes. (DTX 1828 at DKB 017133.)

Apparently not having heard from DeKalb, Dr. Freyssinet reiterated his request on November 10. (Pl.'s Third Mot. In Limine, Ex. F.)

Two days later, on November 12, 1993 Dr. Flick responded – not with further information about test results using RPA's genes – but stating that DeKalb's patent attorneys gave permission for DeKalb to release the information RPA requested "as long as the subject of your patent applications do not overlap ours, i.e., our claims are to the fertile transgenic corn containing these promoters and genes. If your claims are to the genes and promoters there is no problem at all." (DTX 1646 at RPA 023436.)

Finally, on November 30, Dr. Freyssinet wrote Dr. Flick to confirm that "[RPA's] claims will be for genes and promoters and not to fertile transgenic corn." (DTX 1647 at RPA 023434.) Dr. Flick then forwarded the requested

³⁸ On one version of the November 12 DeKalb letter, RPA's Dr. Rick DeRose wrote some comments which reflected his view of the claims. DeKalb argues that these comments support its equitable estoppel defense; however, Dr. DeRose's

information to RPA while again reiterating that RPA may use the information "as long as there are no claims to fertile maize plants." (DTX 43 at RPA 020702.)

During his deposition, Dr. Flick testified about the substance of these communications.

Q: Looking at these same exhibits, and any associated discussions that you had with anyone from RPA, did you understand that DeKalb was entitled to file patent applications to obtain patents that included claims that incorporated RPA's inventors' contributions without naming the RPA inventors?

* * *

Dr. Flick: I don't really know what my understanding was then. I don't know that I was concerned about inventorship.

* * *

Q: Dr. Flick, looking at these exhibits, and considering also the--any associated discussions that you had, do you have any understanding as to whether or not these exhibits or your recollections of discussions have any bearing on whether or not RPA's inventors should be included as joint inventors on any of these four patents?

* * *

Dr. Flick: I don't really have an opinion one way or the other about the inventorship. That's something, as I said before, that I've always left to outside counsel to determine. I don't think I can give you an answer to the question, really.

Q: Is it fair to say that you and Dr. Freyssinet never agreed in 1993 as to who should own or who should be the named inventors on any patents that issued?

comments were part of internal RPA communications, were not communicated to DeKalb, and could not, therefore, mislead DeKalb and be a factor in the consideration of equitable estoppel. <u>See infra</u>, Part B.

Dr. Flick: I don't recall having that discussion with him, but I don't think that I would have been the person who would have had that discussion if it occurred. I was not a business person at that time. I was not in management. That's something that I think would have happened at a higher level than me.

(Pl.'s Third Mot. In Limine at Ex. J; Dep. of Dr. Christopher Flick, June 21, 2000 at 864-66.)

In late 1993 and early 1994, in a greenhouse, DeKalb had succeeded in growing transformed corn plants that contained RPA's RD-125 construct and were resistant to Roundup® herbicide at potentially commercial levels. As mentioned earlier, on February 18, 1994, several months after these letters were exchanged, DeKalb informed RPA for the first time that "[W]e have not only demonstrated that we can use the mutant maize EPSPS gene as a selectable marker in maize, but we have now demonstrated tolerance in transgenic plants in the greenhouse to up to four times the field application recommended by Monsanto for tolerant corn! We will repeat these experiments in the field in the summer of 1994. It is obvious from these results that the mutant maize gene has been the key to success." (PTX 240 at DKB 040277.)

Dr. Freyssinet of RPA responded with a three sentence letter stating: "I thank you for the report on development of glyphosate resistant corn. The results look good[.] I hope they will be confirmed by the field experiments." (PTX 242 at DKB 017113.) Then, on March 10, 1994, DeKalb sent RPA another letter that once again mentioned the summer field trials and the gains in glyphosate tolerance

DeKalb had achieved in the greenhouse with RD-125. (PTX 245 at DKB 017108-09.) In addition, that letter requested RPA's opinion regarding the use of RD-125 for other projects, and also requested a response to the "many questions" that need to be answered regarding the "recent successes" of RD-125. (PTX 245 at DKB 017108-09.)

DeKalb conducted field tests in the summer of 1994, and on September 6, 1994, DeKalb received results from the tests that indicated that corn plants containing RPA's RD-125 were resistant to four times the normal level of Roundup® herbicide. The report from the field testing was not sent to RPA. Rather, on September 7, 1994, Dr. Chris Flick of DeKalb sent RPA a letter which stated, in its entirety, that:

As the results that we have obtained in maize with the glyphosate resistant double mutant maize gene provided by RPA to DeKalb have been very encouraging, we are interested in whether this gene would also function as a selectable marker in soybeans. Is it possible for DeKalb to use this gene in soybeans as a selectable marker?

I will await your answer.

(PTX 310 at RPA 021092.)

In 1994, these letters were the extent of the communications between DeKalb and RPA regarding RD-125 and its introduction into corn lines.

DeKalb never informed RPA directly about the field success of RD-125.39

³⁹ DeKalb's failure to inform RPA of its successes was an issue in the first phase of this case. On April 21, 1999, at the end of the first phase, a jury found that RPA agreed to allow DeKalb to use the RD-125 construct in return for

RPA's first indication that DeKalb had achieved positive results beyond the initial lab tests reported in February 1994 was in December of 1996. Yet, it was not until the Fall of 1997, when Dr. DeRose saw DeKalb's APHIS application for sale of a commercial product, that RPA became aware of DeKalb's commercialization of that material.

В.

The elements of an equitable estoppel defense were established in an *en banc* opinion of the Federal Circuit in A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020 (Fed. Cir. 1992).⁴⁰ The court held the elements to be:

DeKalb's agreement to provide the results of its testing to RPA. The jury found that this agreement existed in three forms: as an oral contract made between Dr. Freyssinet of RPA and Dr. Mackey of DeKalb at the November 1992 meeting; as an implied contract formed by the parties' conduct after the meeting; and as a modification of agreements made in 1985 and 1991. Moreover, the jury found that DeKalb breached this agreement by not providing the results of the Hawaii field tests in the summer of 1994, and that this breach caused RPA to enter another agreement on different terms than it otherwise would have. The jury also found that DeKalb fraudulently induced RPA to enter the 1994 Agreement on the terms that it did.

⁴⁰ RPA contends that the elements of equitable estoppel derive from MCV, Inc. v. King-Seeley Thermos Co., 870 F.2d 1568 (Fed. Cir. 1989). Those elements were first set forth in Jamesbury Corp. v. Litton Indus. Prods., Inc., 839 F.2d 1544, 1553-54 (Fed. Cir. 1988). While RPA is correct that MCV involved a claim of correction of inventorship and Aukerman involved a patent infringement claim, Aukerman "expressly overruled" the equitable estoppel elements used in both Jamesbury and MCV. 960 F.2d at 1042. There was no reservation or limitation to the overruling nor is there any evidence that the test set out by the Aukerman court was to apply only in patent infringement cases. In fact, the Aukerman test has been used by several courts to evaluate an equitable estoppel claim in the context of a claim of joint inventorship. See, e.g., Pannu, 96 F. Supp. 2d at 1368; Ellison Educ. Equip., Inc. v. Chen, 2004 WL 3154592, at *5 (C.D. Cal. Dec. 21,

1) The actor, who usually must have knowledge of the true facts, communicates something in a misleading way, either by words, conduct, or silence. 2) The other relies upon that communication. 3) And the other would be harmed materially if the actor is later permitted to assert any claim inconsistent with his earlier conduct.

<u>Id.</u> at 1041 (quoting D.B. Dobbs, Handbook on the Law of Remedies § 2.3, at 42 (1973)). Absent special circumstances, the party attempting to show equitable estoppel has the burden of proving each of the three elements by a preponderance of the evidence.⁴¹ <u>Aukerman</u>, 960 F.2d at 1046. Here, DeKalb bears that burden.

Because DeKalb relies primarily on the 1993 letters to prevail, that correspondence would have to show that: 1) RPA made a misleading statement to the effect that it would not seek to include any of its employees as inventors on a patent for the same claims that are at issue in this case; 2) DeKalb relied on that miscommunication; and 3) DeKalb would be materially harmed if RPA is allowed to proceed with its claims. Here, DeKalb has failed to establish any of the elements of the Aukerman test.

In the several letters which were exchanged between the parties in 1993,

DeKalb described the subject of its patent or its claims as: "our corn transformation

^{2004);} Williams Serv. Group, Inc. v. O.B. Cannon & Son, Inc., 1994 WL 13850, at *4 (E.D. Pa. Jan. 19, 1994).

⁴¹ While fraud or intentional misconduct qualify as special circumstances, see <u>Aukerman</u>, 960 F.2d at 1046, and there has been an allegation of fraud in this case, the Court need not address whether any higher standard should apply because DeKalb has failed to meet the less stringent preponderance of the evidence test.

patent" (Aug. 5, 12 and 13 letters); "fertile transgenic corn containing [RPA] promoters and genes" (Nov. 12 letter); and "fertile maize plants" (Dec. 2 letter). (DTX595 at RPA 024235-36; DTX 599 at RPA 020678; DTX 608 at RPA 020684; DTX 1646 at RPA 023436; DTX 1648 at RPA 023233.) The declarations sent with the letters refer to transgenic plants which had some resistance to glyphosate following transformation with the Comai aroA gene from salmonella (Example One) but the reference to RPA's mutated maize EPSPS genes was in Example Two and was in terms of its use as a selectable marker, i.e. exemplifying the transformation process. (DTX 599 at RPA 020679-82.)

These terms intimate that the patent DeKalb was discussing in the letters was for the *process* of transforming corn, not for a fertile plant containing RPA's genetic constructs that exhibited resistance to glyphosate. While the declarations that were attached to the first letters do specifically discuss glyphosate resistance, it was in the context of use of RPA's gene as a selectable marker or as evidence of a successful transformation.

The letters must be carefully parsed: The discussion up until the Flick letter of November 12, 1993 was DeKalb seeking permission to publish the DMMG and OTP to exemplify their corn transformation patents. Dr. Flick, in response to Dr. Freyssinet's request for reciprocal permission to disclose DeKalb proprietary information in a prospective RPA patent application, gives permission to RPA to use that information to exemplify the invention of application so long as the patents

RPA wished to apply for were not fertile, transgenic corn plants. This is not the same as asking RPA to waive any rights it might have had to patents DeKalb might apply for in which RPA scientists may have made an inventive contribution. Flick's and Freyssinet's communications were very specific and limited to patents RPA was then contemplating which did not in fact include fertile transgenic plants.

DeKalb stressed that it did not think RPA would mind including such information but that it needed to obtain permission under the Confidentiality Agreement between the parties: "We see no reason why RPA would be concerned about disclosure of this information to the U.S. patent office; however, since this information is covered by our confidentiality agreement we are obligated to obtain your approval." (Aug. 13 letter, DTX 608 at RPA 020684.) The words used by DeKalb to describe its patent and the subjects of its claims simply do not support an inference that RPA could have reasonably interpreted DeKalb's request to encompass a corn plant resistant to normally toxic levels of glyphosate.

Dr. Freyssinet's August 26, 1993 acquiescence in the use of RPA's information ("Rhone-Poulenc agrees with the use of our constructs to exemplify your patent on corn transformation") was conditioned upon DeKalb's reciprocating with information that could be used to exemplify applications for patents for promoters RPA anticipated filing, not for future claims relating to glyphosate resistant corn, the very object of the collaboration. (DTX 617 at DKB 017134 (emphasis added).) The communications were not made in the latter context and

could not reasonably have been received by DeKalb as a statement that RPA was waiving any claim of inventorship to corn made glyphosate resistant by the use of its genes.

Moreover, Dr. Flick's deposition testimony flies in the face of DeKalb's claim that RPA said it would not claim inventorship of a patent for glyphosate resistant corn. Dr. Flick, who was either the sender or recipient of the last three letters stated that he was not concerned about inventorship at the time the correspondence was exchanged and that, in any event, he was not the person who would have been involved with determining who inventors on patents should be. (Flick Dep. 864-66, June 21, 2000.) Both Dr. Flick's testimony and the reasons given by DeKalb for seeking RPA's permission support a finding that RPA had no knowledge the fertile, transgenic plants being discussed exhibited any significant level of resistance to glyphosate and did not convey an intent to abandon any claim it may have had in the development of glyphosate resistant plants.

This is further corroborated by the relationship of the parties. RPA and DeKalb had been in a collaboration with the specific goal of creating corn plants that would exhibit agronomic tolerance to glyphosate – meaning that a corn field could be sprayed with a field application of glyphosate, the weeds killed but the corn not harmed. (DeRose, Trial Tr. vol. I, 140-41.) It was toward that end that RPA had sent the various constructs attached to its OTP to DeKalb in February, 1992. There is no evidence that at any time during the exchange of pertinent

correspondence (August through November, 1993) that DeKalb had given RPA any information about the success of the RPA genes other than cells transformed with those genes having exhibited resistance to glyphosate in the petri dish. (DTX 613 at RPA 028807-09.) It was not until February 18, 1994 that DeKalb communicated to RPA that laboratory and greenhouse tests of regenerated plants had withstood spraying with at least 16 ounces of glyphosate – the amount recommended by Monsanto for field applications. (PTX 240 at DKB 040277-82.) DeKalb knew what it had told RPA and what it had not told RPA. DeKalb could not reasonably have believed that RPA would abandon any claim to glyphosate resistant plants when the development of glyphosate resistant plants was the goal of their collaboration and the quest of many others at the time and RPA had not been informed that DeKalb had succeeded in that endeavor.

As to the third <u>Aukerman</u> element, DeKalb has shown no detrimental effect which the statements conceivably could have had upon the application process or scope or timing of the claims in either the '497 or the '798 patents. <u>Aukerman</u>, 960 F.2d at 1041. Nor has DeKalb shown that it was detrimentally affected by allowing RPA to use earlier information in seeking patents on genes and promoters.

The defense of equitable estoppel is a matter committed to the sound discretion of the trial judge. Aukerman, 960 F.2d at 1028. It "is not limited to a particular factual situation nor subject to resolution by simple or hard and fast rules. At most, courts have provided general guidelines based on fact patterns which have

been litigated, albeit attempting to provide a unifying set of principles." Id. at 1041. In assessing an equitable estoppel defense, a court must also take into consideration any evidence and facts (in addition to those which relate to the three elements outlined in Aukerman) which bear on the equities of the parties. Id. at 1043.

This Court finds that there are no other factors in this case which would warrant a finding of equitable estoppel. DeKalb simply failed to show that RPA made misleading statements or that DeKalb could have reasonably interpreted those statements in a detrimental way or that as a result of those statements it has suffered actual detriment.

V. CONCLUSION

In light of the above discussion, the Court will instruct the Director of the Patent and Trademark Office to add Rick DeRose, Georges Freyssinet, Michel Lebrun, Bernard Leroux, and Alain Sailland as joint inventors of U.S. Patent 6,040,497 (dated March 21, 2000). However, for U.S. Patent 5,554,798 (dated September 10, 1996) it is determined that conception had occurred prior to any of

the applicants making a significant inventive contribution and that their application to be added as joint inventors on that patent should be denied.

This the day of August 7, 2006

/s/ N. Carlton Tilley, Jr.
United States District Judge